VACCINIA-PSA PHASE I CLINICAL TRIAL

Precis

This trial will evaluate in patients with metastatic prostate cancer the tolerability, toxicities, efficacy, and immunologic effects of repeated vaccinations with a recombinant vaccinia virus that contains the Prostate Specific Antigen gene (PROSTVAC). Patients with PSA-expressing adenocarcinoma of the prostate will be evaluated for eligibility that includes a history of prior vaccinia (as vaccine against smallpox) and immunocompetence. We completed a phase I trial investigating the use of rV-CEA in adenocarcinomas of the GI tract, lung and breast. The toxicities encountered are local reactions to the vaccine. We did not encounter any myelosuppression or systemic autoimmune reaction. Though PSA is confined to the prostatic cells, we would like to evaluate two doses to ensure safety and to decide a best biological dose. Six patients will receive 1 x 10^6 PFU of vaccine, and six will receive 1.0 X 10^7 PFU. We plan to give three vaccinations at one month intervals. Intrapatient escalation (increased the dose on second or third vaccination in the same patient) will be dependent on the cellular response, determined by laboratory studies, to the inoculation. All six patients treated in the first dose level must be evaluable for 4 weeks before enrolling patients at the higher dose level. Toxicity, tumor response, and humoral and cellular immunity factors will be monitored. Once we determined the best biological dose, we would like to accrue an additional 6 patients to that level. In our rV-CEA trial, we were able to isolate CD 8+ cell against CEA in HLA A2 patients. Since 50% of the population is positive for HLA A2, we would like to better evaluate the immunologic response in this population.